

**NONPROVISIONAL APPLICATION FOR LETTERS PATENT
UNITED STATES OF AMERICA**

5 Be it known that we, **IN HWAN YEO**, residing at **26 Leno Mills Avenue, Richmond Hill, Ontario L4S1J6, Canada**, a citizen of the Republic of Korea, **SANDRA MCINTOSH**, residing at **110 Rossiter Court, Athens, Georgia 30606**, a citizen of the
10 United States of America, **CHRIS C.K. WANG**, residing at **3480 Evens Ridge Drive, Chamblee, Georgia 30341** a citizen of the United States of America, and **AKBAR BEIKI-ARDAKANI**, residing at **47 Aberfeldy Crescent, Thornhill, Ontario L3T4C1, Canada**, a citizen of Canada, have invented certain new and useful
15 improvements in a

MEDICAL PHANTOM, HOLDER AND METHOD OF USE THEREOF

20 of which the following is a specification:

INVENTORS' REPRESENTATIVES

**JOEL D. MYERS, ESQ.
THOMAS R. WILLIAMSON III, ESQ.**

**MYERS & KAPLAN
INTELLECTUAL PROPERTY LAW, L.L.C.
1899 Powers Ferry Road
Suite 310
Atlanta, GA 30339
Telephone: (770) 541-7444
Facsimile: (770) 541-7448
Email: jmyers@mkiplaw.com
Email: twilliamson@mkiplaw.com**

MEDICAL PHANTOM, HOLDER AND METHOD OF USE THEREOF**TECHNICAL FIELD**

5 The present invention relates generally to an apparatus and method for simulating human tissue (or water) for the purpose of estimating and/or calibrating dose levels due to x-ray exposure prior to exposing a patient thereto. More specifically, the present invention relates to a composition
10 and construction for forming a filtering apparatus to reduce x-ray film over-response to photon beams, wherein the apparatus comprises a cassette, or a water phantom, incorporating lead foil and water (or water-equivalent plastic or polymer), or alternately lead particles admixed with a
15 water-equivalent plastic or polymer material, wherein the cassette, or a water phantom, is enclosed in a carrier for facilitating insertion into, positioning in, and removal from, x-ray equipment. The present invention is particularly advantageous in providing an easily handled cassette phantom
20 and holder, allowing rapid and easy setup in x-ray equipment.

BACKGROUND OF THE INVENTION

Dosimetry of radiotherapy treatment beams is rapidly becoming a very important procedure because successful
5 radiation therapy requires an accurate delivery of a targeted dose to a cancerous volume of tissue. For example, it has been found that a dose delivery 10%-15% below the target will result in a two- to three-fold decrease in the chance of cure, while delivery of a dose higher than the target increases the
10 chance of irreversible damage by overexposure to x-rays. Therefore, accurate and specific dose levels are critical to the success rate of patient treatment.

One such method of treating patients with x-radiation is
15 Intensity Modulated Radiation Therapy (IMRT). With IMRT, the radiation is delivered as thousands of tiny, pencil-thin radiation beams (i.e. beamlets), wherein the beams enter the body from many angles to destroy cancer cells with accuracy. This accurate delivery of beamlets permits a higher dose of
20 radiation to be delivered to tumors and limits the dose to surrounding healthy tissue, thereby reducing radiation side effects. In this fashion, IMRT can be utilized to safely

treat tumors located near critical organs, such as the eye and spinal cord.

The positions of IMRT beams targeted to the tumor of
5 concern are computationally optimized based on the computed
tomography image of a patient. Computed tomography, or CT, is
an x-ray diagnostic procedure utilized to generate a three-
dimensional image of a patient, wherein the resulting image is
composed of a multitude of cross-sectional views. CT requires
10 data acquisition, image reconstruction and image display. To
collect data, x-rays are passed through a patient and are
attenuated within the patient, wherein the resulting levels of
x-rays are sensed by external detectors to allow the creation
of a detailed image of the internal composition of the
15 patient. By moving the x-ray source and taking multiple
images, detailed cross-sections can be produced, which then
can be utilized to form a three-dimensional image of the
patient for accurate selection of the target area to be
treated.

20

Once the CT image has been formed and the target area
position elucidated and selected, radiation therapy can be
planned. In the planning, radiation beams and beamlets are

optimized. Prior to performing IMRT, verification of the radiation levels for the therapy is performed. Typically, a phantom, or tissue mimic, is utilized to assist in such verification. First, beams that were optimized for patient
5 treatment are delivered upon a flat phantom and the consequent dose distributions at some specific depth are calculated for each beam. Second, beams are actually delivered on a phantom that houses x-ray film under a medical linear accelerator, thereby generating images on the films. The images are
10 converted into a dose distribution, which is then compared with the dose distribution obtained by calculation. If the difference between the calculations and the actual measurements are within acceptable parameters, the treatment based on the computationally optimized beam commences on a
15 patient.

As explained in the previous paragraph, in order to achieve and/or confirm the target beam delivery, successful radiotherapy requires accurate dosimetry for treatment
20 verification. Existing dosimeters, such as ion chambers, thermoluminescence dosimeters, and diodes, each have drawbacks including relatively long measurement time and poor spatial resolution.

An ionization chamber (IC)/water-equivalent phantom system has been recommended for isodose distribution measurement. However, ICs have some shortcomings in utilization. Measurement with an IC provides only selective information with poor spatial resolution; that is, each data point is limited by the volume of the IC and the spacing between measurements. In addition, utilization of an IC typically requires a disadvantageously long measurement time.

Another method, via dynamic beam defining collimators or wedges, has complicated dose measurement using an IC. For dynamic-wedged beam dosimetry, a large array of ICs must be used to simultaneously measure doses at various positions in a phantom. In addition to an economic disadvantage, the simultaneous placement of a large number of ICs in a phantom alters the dose distribution being measured. The same disadvantages also apply to thermoluminescence dosimeters (TLDs) and diode detectors. Thus improved dosimetry methods are desirable. X-ray film may be utilized for this purpose, as it possesses the required properties discussed above as a dosimeter. However, it has heretofore been clinically questionable as a dosimeter for photon beams because, due to

its silver bromide formulation, it over-responds to photons with energies below about 400 keV.

Film dosimetry, in general, can be utilized for
5 measurement of megavoltage x-rays and thus contributes to the general quality assurance of traditional radiation therapy. The accuracy of film dosimetry for the specific verification of x-rays has been found to have an associated potential error as high as 10-20% for IMRT. Such an error level significantly
10 exceeds the required dosimetric accuracy for radiation therapy. As will be more fully detailed hereunder, film dosimetry can be improved significantly by utilizing a cassette or a phantom that houses filters, wherein the filters prevent low-energy photons from reaching the film, thus
15 obviating film over-response, the typical source of error. In this fashion, film dosimetry can be utilized for verification of radiation therapy.

There are various devices and methods available for
20 creating medical phantoms, or mimics to water (or human tissue) for film dosimetry, wherein the different phantoms may be utilized for different types of analytical techniques. Each, however, is disadvantageous when compared to the present

invention, as the large error associated with film dosimetry is still present.

As will be readily seen from the description below, the present invention differs from the previous use of intensifying screens based on lead or high atomic number materials in film cassettes, wherein previous uses have restricted films to placement in contact with the screens and imaging. On the contrary, the current invention provides spacing between the film and the filters with the goal of accurate radiation dosimetry (or measurement).

Other assemblies have been utilized wherein stacks of tissue-equivalent materials are placed together along with lead foil with spacing from the film. Such devices suffer from a lack of reproducibility and because they are not integral units, they are not readily handled without great care. Previously, the idea of adding lead powder in the phantom was realized. However, such realization was not rigorous in that the phantom was embrittled and thus not practically durable. In addition, the phantom was not water- or tissue-equivalent.

Therefore, it is readily apparent that there is a need for a medical phantom device and method for filtration of photons, capable of enabling the utilization of a film cassette and a phantom mimicking human tissue and containing
5 x-ray film for radiation dose measurement, thereby avoiding the above-discussed disadvantages. There is a further need for a device to hold such a medical phantom for insertion, alignment and removal. As will be more fully detailed hereinbelow, it is to the provision of such an apparatus with
10 holder that the present invention is directed.

BRIEF SUMMARY OF THE INVENTION

Briefly described, in a preferred embodiment, the present
15 invention overcomes the above-mentioned disadvantages and meets the recognized need for such a device and method by providing embodiments directed to a medical phantom cassette for use with x-ray film, wherein the cassette includes lead, preferably in the form of foil, predisposed within the
20 cassette body. The cassette is installed within a holding device that can readily be inserted into medical equipment, aligned therewithin, and removed upon completion of verification of the correct dose for patient treatment

According to its major aspects and broadly stated, the present invention, in its preferred form, is a medical phantom cassette and method for mimicking human tissue for the purpose of verification of medical apparatus, particularly x-ray equipment for IMRT, such as a medical linear accelerator and radiation therapy. The cassette includes two sections, each having a water-equivalent material construction, wherein the sections retain a piece of x-ray film when closed together. The cassette is retained within a holding cartridge that enables compression of the medical phantom and x-ray film, wherein the holding cartridge has legs for height adjustment for adaptable setup within an x-ray machine.

More specifically, the present invention is a composition of materials that filters x-ray photons and that can be formed into a suitable prismatic film dosimetry cassette. The two-section cassette has filters located within the body of each section, wherein the top, bottom and side surfaces of the sections form a generally rectangular-shaped prism. The bodies of the sections are fabricated from tissue-equivalent plastic or polymeric materials, such as, for exemplary purposes only, polystyrene or water-equivalent plastic, which

serves to mimic human tissue when bombarded by photons. The sections are hingably attached to facilitate opening and closing, and the filters are made of a high atomic weight element sheet material.

5

In use, film is inserted between the sections and the cassette is closed with the film retained therein. The film-containing cassette can then be augmented with additional slabs of tissue mimicking material, such as, for exemplary
10 purposes only, a sandwich of polystyrene slabs or slabs of water-equivalent material. Following such augmentation, the cassette is placed within a holder for positioning within an x-ray machine, wherein the holder facilitates compression and height positioning adjusting setup parameters such as
15 alignment and flatness.

The present invention also includes the idea of a water-equivalent phantom containing the elements of filtering materials, such as lead or high atomic number materials,
20 uniformly distributed in a phantom body. Film can be sandwiched in between the slabs of the phantom composed of the mixture of plastic materials and high atomic number elements. The size and shape of the phantom can be determined depending

on the application (simulation of a rectangular water phantom or any human organ).

A feature and advantage of the present invention is its ability to mimic human tissue in any desired shape to enable accurate measurement of x-ray dose for radiation therapy verification such as IMRT, and additionally the calibration of x-ray equipment.

A feature and advantage of the present invention is its ability to accurately verify the planned dose delivery to a patient and help prevent over- and under-exposure of a patient to radiation.

A further feature and advantage of the present invention is that it facilitates easy insertion into, and removal from, x-ray equipment.

An additional feature and advantage of the present invention is its ability to be adjusted while positioned within medical equipment.

A further feature and advantage of the present invention is its ease of use, manufacture and low cost of production.

These and other features and advantages of the present invention will become more apparent to one skilled in the art from the following description and claims when read in light of the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Having thus described the invention in general terms, the present invention will be better understood by reading the Detailed Description of the Preferred and Selected Alternate Embodiments with reference to the accompanying drawing figures, which are not necessarily drawn to scale, and in which like reference numerals denote similar structures and refer to like elements throughout, and in which:

FIG. 1A depicts a film dosimetry cassette according to a preferred embodiment of the present invention;

FIG. 1B depicts the film dosimetry cassette of **FIG. 1A** with a sheet of film retained therein;

FIG. 2 depicts the film dosimetry cassette device of **FIG 1B** showing an augmented phantom set;

5 **FIG. 3A** depicts a device for holding the construction of **FIG. 1A** according to a preferred embodiment of the present invention;

FIG. 3B depicts the device of **FIG. 2** within the holding
10 device of **FIG. 3A** according to a preferred embodiment of the present invention; and

FIG. 4 depicts an alternate embodiment of the present invention.

15
DETAILED DESCRIPTION OF THE PREFERRED AND SELECTED ALTERNATE

EMBODIMENTS

In describing the preferred and selected alternate
20 embodiments of the present invention, as illustrated in the Figures, specific terminology is employed for the sake of clarity. The invention, however, is not intended to be limited to the specific terminology so selected, and it is to

be understood that each specific element includes all technical equivalents that operate in a similar manner to accomplish similar functions.

5 Referring now to **FIGS. 1A** and **1B** and the preferred form of the present invention, cassette **100** is preferably a prismatic film dosimetry cassette comprising first section **110** and second section **120**. First section **110** preferably comprises top surface **112**, bottom surface **114**, side surfaces
10 **116**, body **117** and filter **118**, and second section **120** preferably comprises top surface **122**, bottom surface **124**, side surfaces **126**, body **127** and filter **128**. Top surfaces **112** and **122**, bottom surfaces **114** and **124** and side surfaces **116** and **126** of first and second sections **110** and **120**, respectively,
15 preferably form a generally rectangular-shaped prism, wherein bodies **117** and **127** are preferably fabricated from a plastic or polymeric material, such as, for exemplary purposes only, polystyrene plastic or other water- or tissue-equivalent material. First section **110** and second section **120** are
20 preferably integral units and are hingably attached via hinge **130** in order to preferably facilitate alignment and closure. Filters **118** and **128** preferably comprise a sheet of high atomic weight element material, such as, for exemplary purposes only,

lead foil, wherein filters **118** and **128** are preferably integral to first section **110** and section **120**, respectively.

First section **110** and second section **120** are preferably
5 comprised of bodies **117** and **127**, respectively, wherein bodies
117 and **127** preferably serve to mimic human tissue when
bombarded by photons. Filters **118** and **128** are preferably
located within first section **110** and second section **120**,
respectively, preferably within bodies **117** and **127**,
10 respectively. Filter **118** is preferably carried at a distance
of approximately 0.6cm from bottom **114** of first section **110**
and filter **128** is preferably carried at approximately 0.6cm
from top **122** of second section **120**. Although such positioning
of filters **118** and **128** is preferred, other positions could be
15 utilized, either closer or farther from the top or bottom of
either or both sections.

The hinged relationship of first section **110** and second
section **120** of cassette **100** preferably enables the placement
20 and fixable retention of film **140** therewithin.

Referring now to **FIG. 2**, cassette **100** containing film **140**
is preferably positioned within slabs **210** comprising augmented

phantom 200, wherein slabs 210 are preferably formed from tissue-mimicking material, such as, for exemplary purposes only, a sandwich of polystyrene slabs or other water- or tissue-equivalent material. At least one slab 210 is preferably positioned proximate top surface 112 of first section 110 and at least one slab 210 is preferably positioned proximate bottom surface 124 of second section 120, wherein slabs 210 and cassette 100 preferably form a sandwich construction.

10

Referring now to FIG. 3A, holder 300 is preferably defined by base 310, side wall 320, side wall 330, front wall 340 and back wall 350, and holder 300 is preferably formed from clear plastic materials. Compression device 360, preferably located within back wall 350, preferably has handle 362, threaded shaft 364, threaded bushing 366 and compression plate 368. Threaded bushing 366 is preferably retained within back wall 350.

15

Referring now to FIG. 3B, the cassette 100/phantom 200 combination as shown in FIG. 2 is preferably positioned in holder 300 and preferably compressed via application of force preferably by turning handle 362 of compression device 360.

20

Front wall **340** preferably has opening **370** defined therein to preferably permit entry of photon beam **B**. Rulers **380** and **382** are preferably located atop side walls **330** and **320**, respectively, to preferably enable measurement of the extent of compression and reproducibility of a selected cassette **100**/phantom **200** arrangement. Legs **390** are preferably attached to base **310**, wherein legs **390** preferably enable height adjustment via mechanism **395**, wherein mechanism **395** is, for exemplary purposes only, a screw adjustment.

10

In use, calculated values are preferably obtained for a beam delivered on simulated water-equivalent phantom **200** located perpendicular to, or parallel with, beam **B**. Holder **300**, with cassette **100** therein, is then preferably positioned within an x-ray machine, such as, for exemplary purposes only, a medical linear accelerator. Mechanism **395** is preferably subsequently utilized to adjust the height of holder **300** within the x-ray machine, thereby preferably facilitating accurate actual dosage measurement by film exposure to radiation. In this fashion, x-ray film is preferably exposed to a known radiation dose, and correlation with the calculated dosage values is preferably verified by utilizing the exposure

20

determined from the film. Once verified, human exposure at known quantified levels preferably takes place.

It is envisioned in an alternate embodiment represented
5 by **FIG. 4** that phantom **400** of the present invention could be formed from a composition of high atomic number powder **410** and plastic or polymeric compound **420**, wherein high atomic number powder **410** comprises, for exemplary purposes only, lead and/or tungsten powder, or other Group VI element from the periodic
10 table, thereby making the entire phantom tissue-equivalent. The high atomic number powder could comprise, for example, approximately between 5 to 6 percent by weight if lead or tungsten is utilized. Other high atomic number powders, and combinations thereof, could be utilized for this embodiment of
15 the present invention, and the percentage composition could require variation for use with powders other than lead and/or tungsten. The preferred, but not limiting to, elemental composition in weight percent is approximately 80.5% for carbon (C), approximately 13.5% for hydrogen (H), and
20 approximately 6.0% for tungsten (W).

In this embodiment, high atomic number powder **410** and plastic or polymer **420** could be mixed together to form phantom

slabs **430** and **440**, wherein phantom slabs **430** and **440** comprise the entire phantom and could be placed on opposing sides of x-ray film **450**, in order to prevent overresponse of the x-ray film. Phantom slabs **430** and **440** thereby form phantom **400**,
5 wherein phantom **400** is suitable for mimicking human tissue in response to a photon beam **B** without requiring augmentation. Phantom **400** could then be utilized for verification of the intensity of radiation beams for patient treatment as is further described hereinbelow.

10

In operation of the various embodiments of the present invention hereinabove, the intensity of radiation beams intended for patient treatment can be verified by 1) obtaining a cassette or a phantom of the present invention for mimicking
15 human tissue; 2) computationally delivering the radiation beams intended for patient treatment on the surface of a simulated tissue- or water-equivalent phantom; 3) calculating the dose distributions at a specific depth below the surface of the phantom for each beam component; 4) setting up
20 radiation beams for actual delivery on radiographic film, using either a cassette in an augmented phantom or stand-alone phantom of the present invention to house the film; 5) delivering an actual radiation beam intended for patient

treatment onto the augmented or the phantom of the present invention, whereby images are generated on the film; 6) converting the images into equivalent actual dose distributions; 7) comparing the actual dose distributions with the calculated dose distributions; and 8) determining whether the differences between the calculated values and the values from actual images are within acceptable levels. Finally, a patient is preferably treated using the verified beams.

It is envisioned in an alternate embodiment that a high atomic number powder could be mixed with a tissue- or water-equivalent plastic or polymer and formed into a humanoid shape.

The foregoing description and drawings comprise illustrative embodiments of the present invention. Having thus described exemplary embodiments of the present invention, it should be noted by those skilled in the art that the within disclosures are exemplary only, and that various other alternatives, adaptations, and modifications may be made within the scope of the present invention. Merely numbering or listing the steps of a method in a certain order does not constitute any limitation on the order of the steps of that

method. Many modifications and other embodiments of the invention will come to mind to one skilled in the art to which this invention pertains having the benefit of the teachings presented in the foregoing descriptions and the associated
5 drawings. Although specific terms may be employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation. Accordingly, the present invention is not limited to the specific embodiments illustrated herein, but is limited only by the following
10 claims.